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SH	AA	6,030,990	02/29/00	Maeda e						
54	AB	6,166,049	12/26/00	Smith et						
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	OT	HER DOCUMENT						ges, Et	c.)	
-SM	AM		glitazone, D	rugs of th	e Future,	2002, 27(2): 1	32-139			
84	AN	Michel Farnier, Nou MT Endocrinologie,			édicamer	nteuses dans le	traitemer	nt des dys	slipidém	ies,
SH	AO	Berger et al., Physio	logical and	Therapeu				tor-Activa	ited	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTY. DOCKET NO.: CV01489K APPLICANT:

SERIAL NO.: 10/057,323

INFORMATION DISCLOSURE STATEMENT

Harry R. Davis, et al.

	BY APPLICANT				Harry R. Davis, et al.				
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SM		Active Inhibitor of C	holesterol A	Absorption, <i>J. Med. Chem.</i> 41 :973-980 (1998)					
	AR	Gilbert R. Thompso	n et al., Nov	el lipid-regulating	drugs, Exp. Op	in. Invest.	Drugs 9	(11):261	9-
		2628 (2000)							
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'		Absorption Inhibitor	. Ezetimibe.	in Combination V	Vith 3-Hydroxy-	3-Methylgl	utaryl Co	enzyme	Α
	i .	Reductase Inhibitor	s in Dogs, A	/letabolism 50 (10):1234-1241 (20	001)			
· ·	ΑU	Study Showed Ezet	imibe Signif	icantly Reduced I	evels of LDL C	holesterol	or "Bad"	Choleste	erol in
Ì		Patients, Schering-I	Plough Pres	s Release					_
	ΑV	T. Kosoglou et al., F	Pharmacody	namic Interaction	Between Feno	fibrate and	the Cho	lesterol	
		Absorption Inhibitor	Ezetimibe.	Atherosclerosis (2):38 (2001)				
	AW	Remington's Pharm	raceutical Si	ciences, 18 [™] ed. 1	1990 p. 1319, 10	33-1647			
	AX	Baker S G et al., Tr	eatment of I	nomozygous fami	lial hypercholes	terolaemia	with pro	bucol, S	outh
<u> </u>		African Medical Jou	rnal (1982)						
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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APPLICANT:	
Harry R. Davis, et al.	
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34		Exhibit A: SCH 58235 Micronized (ezetimibe), D		
	AB	Exhibit B: SCH 58235 (ezetimibe), Drug Formula	ation Development Sumn	nary
	AC	Exhibit C: SCH 58235 (ezetimibe), Drug Formula	ation Development Sumn	nary
	AD	Exhibit D: SCH 58235 (ezetimibe), Drug Formula	ation Development Sumn	nary
	AE	Exhibit E: SCH 58235 (ezetimibe), Drug Formula		
	AF	Exhibit F: SCH 58235 (ezetimibe), Drug Formula		
	AG	Exhibit G: SCH 58235 (ezetimibe), Drug Formula	ation Development Sumr	nary
	AH	Exhibit H: SCH 58235 (ezetimibe), Drug Formula		
1 1	Al	Exhibit 1: Master Sheet for the SCH 58235 and		dy, Schering-Plough
	<u> </u>	Research Institute (Protocol No. C906-411), page		
1 1	AJ	Exhibit 2: Medical Research Study #1055/97, SC		
1 1	1	of Two Prototype Tablet Formulations and the Re		
1 1		Normal Male Volunteers: A Four Way Crossover	Study #C97-221-01, Info	rmed Consent,
 	AK	Peninsular Testing Corporation, page 106-112	anah Childi "A Dhasa II f	Davids Died Dass
\ {	An	Exhibit 3: Consent Form to Participate in a Rese Response Investigation of Efficacy and Safety of I		
	İ	Placebo in Subjects with Primary Hypercholestero		
1	ł	(Protocol No. C98-010), page 1558-1566	ieijila, Schenng-Flough	Nescarcii ilistitute
	AL	Exhibit 4: Medical Research Study #1096/99, SC	H 58235: Pharmacoking	etic Pharmacodynamic
1 1	} ` `~	Drug Interaction Study with Digoxin in Healthy Vol		
	1	Peninsular Testing Corporation, page 124-130		·
	AM	Exhibit 5: Informed Consent, "SCH 58235: Asse	essment of Multiple-Dose	Drug Interaction
501	1 .	Between 58235 and Gemfibrozil in Healthy Volunt	eers," Schering-Plough F	Research Institute, page
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APR 1 0 2003 FORM PTO-1449 ATTY. DOCKET NO .: SERIAL NO.: U.S. DEPARTMENT OF COMMERCE 10/057,323 PATENT AND TRADEMARK OFFICE PADE CV01489K APPLICANT: INFORMATION DISCLOSURE STATEMENT Harry R. Davis et al. BY APPLICANT FILING DATE: GROUP:1617 (Use several sheets if necessary) January 25, 2002 1619 U.S. PATENT DOCUMENTS FILING DATE IF APPROPRIATE EXAMINER DOCUMENT DATE NAME CLASS SUB-INITIAL SVI NUMBER CLASS 01/16/03 | Iqbal et al. US2003/0013729 514 AA AB AC AD AE AF AG АН ΑI TECH CENTER 1600/2900 AL AK FOREIGN PATENT DOCUMENTS DOCUMENT DATE COUNTRY CLASS SUB-TRANSLATION NUMBER CLASS YES NO WO 03/018024 31/55 AL 03/06/03 PCT A61K ÀΜ WO 03/018059 03/06/03 PCT A61K 45/06 AN ΑO AP OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) AQ AR AS AT ΑÜ AV **EXAMINER** DATE CONSIDERED 0

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FORM PTO 4449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO.: SERIAL NO.: CV01489K PATENT AND TRADEMARK OFFICE 10/057,323 APPLICANT: INFORMATION DISCLOSURE STATEMENT Harry R. Davis et al. BY APPLICANT FILING DATE: GROUP:1617 (Use several sheets if necessary) January 25, 2002 1619 U.S. PATENT DOCUMENTS EXAMINER DOCUMENT DATE NAME CLASS SUB-FILING DATE IF INITIAL NUMBER CLASS APPROPRIATE AΆ AB AC AD ΑĘ AF AG AH AI ÂĴ ΑK FOREIGN PATENT DOCUMENTS DOCUMENT COUNTRY DATE CLASS SUB-TRANSLATION NUMBER **CLASS** YES NO AL WO96/19450 06/27/96 PCT C07D 205/08 AM WO02/081454 10/17/02 PCT C07D 239/36 AN WO02/26729 -04/04/02 PCT C07D 311/66 AO WO02/64094 08/22/02 A61K AP OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Gilber R. Thompson et al., Novel lipid-regulating drugs, Ashley Publications Ltd. ISSN 1354-3784, 2000, pp. 2619-2628 AR Belamarich P.F. et al., Response to diet and cholestyramine in a patient with sitosterolemia. Pediatrics, ISSN 0031-4005, Dec. 1990 AS Salen G. et al., Lethal atherosclerosis associated with abnormal plasma and tissue sterol SH composition in sitosterolemia with xanthomatosis, Journal of lipid research, ISSN 0022-2275, Sept. 1985 AT ΑU AV **EXAMINER** DATE CONSIDERED *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to

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Sheet __1__ of __8__

FORM PTO-144 SO PARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.: SERIAL NO.: CV01489K 10/057,323
APPLICANT: Harry R. Davis et al.

FILING DATE: GROUP: January 25, 2002 1619

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FORM PTO-1449 PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.: CV01489K APPLICANT: Harry R. Davis et al.

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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FORM PTO-14 TRADENAN U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: SERIAL NO.: 10/057,323 CV01489K APPLICANT: Harry R. Davis et al.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT FILING DATE: GROUP: (Use several sheets if necessary) 1619 January 25, 2002 31/19 X(abs.) **A61K** 11/02/95 PCT WO 95/28919 Dυ 51 15/12 **C12N** PCT WO 96/00288 01/04/96 DV 31/58 **A61K** DW WO 96/09827 04/04/96 PCT 205/08 PCT C07D WO 96/16037 05/30/96 $\overline{\mathsf{DX}}$ A61K 31/35 07/04/96 PCT WO 96/19987 DY 45/06 A61K PCT DZ WO 96/40255 12/19/96 3/04 WO 97/16455 05/09/97 PCT **C07H** EΑ C12N 15/00 05/22/97 PCT WO 97/18304 FB A61K 31/42 WO 97/25042 07/17/97 PCT EC 08/07/97 PCT **C07D** 307/79 WO 97/28149 ED 263/56 C07D 09/04/97 PCT WO 97/31907 EE **A61K** 31/44 WO 97/35576 10/02/97 PCT EF RECEIVED A61K 31/245 EG WO 97/46238 12/11/97 PCT PCT A61K 01/15/98 EΗ WO 98/01100 MAR 1 3 2003 31/45 02/12/98 PCT A61K WO 98/05331 E١ A61K 9/50 04/09/98 PCT EJ WO 98/14179 TECH CENTER 1600/290 A61K 31/19 ĒΚ WO 98/31360 07/23/98 PCT **A61K** 31/215 X(abs.) WO 98/31361 07/23/98 PCT EL A61K 31/445 PCT EМ WO 98/31366 07/23/98 WO 98/43081 10/01/98 PCT **G01N** 33/50 ĒΝ A61K 9/20 10/22/98 PCT ĒΟ WO 98/46215 **A61K** 31/715 ΕP WO 98/47518 10/29/98 PCT EQ WO 98/57652 12/23/98 PCT **A61K** 31/785 45/00 04/02/99 PCT A61K X(abs.) ER WO 99/04815 31/00 WO 99/06035 02/11/99 PCT A61K ES 31/455 WO 99/06046 PCT A61K FT 02/11/99 A61K 31/00 ΕŪ WO 99/09967 03/04/99 PCT WO 99/12534 03/18/99 PCT A61K 31/17 X(abs.) EΥ 31/40 PCT **A61K** EW WO 99/11260 03/11/99 PCT WO 99/15159 04/01/99 **A61K** 31/00 EX 04/01/99 PCT **C07D** 319/20 X(abs.) EY WO 99/15520 C07D 205/08 EZ WO 99/18072 04/15/99 PCT FA WO 99/20275 04/29/99 PCT A61K 31/47 265/36 PCT C07D FB WO 99/20614 04/29/99 9/107 WO 99/29300 PCT A61K FC 06/17/99 WO 99/38498 08/05/99 PCT A61K 31/00 FN C07D 213/65 FE WO 99/38845 08/05/99 PCT 237/32 FF WO 99/38850 08/05/99 PCT **C07D** 62/34 X(abs.) PCT C07C FG WO 99/46232 09/16/99 A61K 9/16 FH WO 99/47123 09/23/99 PCT A61K 31/00 Fi WO 99/48488 09/30/99 PCT 31/405 PCT **A61K** FJ WO 99/66929 12/29/99 31/405 WO 99/66930 12/29/99 PCT **A61K** FK C07D 319/06 01/27/00 PCT FL WO 00/04011 **A61K** 38/26 WO 00/07617 02/17/00 PCT FM

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Electronic Information Discl Statement

COMBINATIONS OF PEROXISON PROLIFERATOR-ACTIVATED RECEPTOR (PPAR) ACTIVATOR(S) AND STEROL ABSORPTION INHIBITOR(S) AND TREATMENTS FOR VASCULAR **INDICATIONS**

Application:

Confirmation:

1525

Applicant(s):

Harry Davis

Docket

Number:

CV01489K

Group Art Unit: 1617

Examiner:

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search string:

(6262042 or 6262047 or 6262098 or 6242605 or 6277584 or 6316029 or RE37721 or

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Note: Applicant is not required to submit a paper copy of cited US Patent Documents

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